

AMENDMENT NO. 1 MAY 2018
TO
IS 10829 : 1993 X-RAY DETECTABLE GAUZE SWABS
AND LAPAROTOMY SPONGES — SPECIFICATION

(First Revision)

(Page 1, clause 2.1) — Substitute the following for the existing:

‘2.1 The following standards are necessary adjuncts to this standard:

<i>IS No.</i>	<i>Title</i>
1963 : 1981	Methods for determination of threads per unit length in woven fabrics (<i>second revision</i>)
1964 : 2001	Textile — Methods for determination of mass per unit length and mass per unit area of fabrics (<i>second revision</i>)
2369 : 1967	Method for determination of absorbency of absorbent textile materials
10150 : 1981	Guide for sterilization of medical products’

(Page 2, Table 1, *Sl No.* ii) *col 4*) — Substitute ‘IS 1964 : 2001 for ‘IS 1964 : 1970’.

(Page 2, Table 1, *Sl No.* iii) *col 4*) — Substitute ‘Test shall be carried out as per IS 2369’ for ‘Pharmacopoeia of India (*Ed. 1985*) (*p A-113*)’.

(Page 2, Table 1, *Sl No.* iv) *col 4*) — Substitute ‘Test shall be carried out as per Annex A’ for ‘Pharmacopoeia of India (*Ed. 1985*) (*p A-138*)’.

(Page 2, Table 1, *Sl No.* v) *col 4*) — Substitute ‘Test shall be carried out as per Annex B’ for ‘British Pharmaceutical Codex (1973) (*p 914*)’.

(Page 2, clause 6.1) — Substitute the following for the existing:

‘6.1 The gauge swabs and laparotomy sponges shall satisfy the test for X-ray opacity in accordance with the method specified in Annex C.’

(Page 2, clause 7.1.1) — Substitute the following for the existing:

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‘7.1.1 The sterilized X-ray detectable gauze swabs and laparotomy sponges shall comply with the test for sterility specified in IS 10150.

(Page 2, clause 9) — Insert Annexes A, B and C after 9.1.1.

ANNEX A

[Clause 5.1, Table 1, Sl No. iii)]

TEST METHOD FOR WATER SOLUBLE SUBSTANCES

A-1 APPARATUS

A-1.1 Weighing balance of suitable range and least count of 0.1 g.

A-1.2 Two beakers capacity of 1000 ml.

A-1.3 Stop watch least count of 1 s.

A-1.4 Stove/hot plate.

A-1.5 A glass rod and filter paper.

A-1.6 Hot air oven [temperature range up to 120° C]

A-2 TEST METHOD

Take a test piece from the sample under test of approximately 7 g and weigh accurately. Fill the beaker with water approximately 700 ml and boil the test piece in the water for 30 min. Stir the water frequently and replace the water loss during evaporation. Decant the liquid into a beaker, squeeze the residual liquid from the material carefully with a glass rod, mix the liquids and filter the extract whilst hot. Evaporate the filtrate and dry the residue to constant weight at 100° C to 105° C. Calculate the percentage of water soluble content by weighing the weight of residue dried at constant weight with the weight of sample as given below:

$$\text{Water soluble substance, percent by weight} = \frac{\text{Mass of the residue}}{\text{Mass of the sample}} \times 100$$

ANNEX B

[*Clause 5.1, Table 1, Sl No. iv*)]

TEST METHOD FOR FOREIGN MATTER

B-1 APPARATUS

Weighing balance of suitable range and least count of 0.1 g.

B-2 TEST METHOD

Weigh 100 to 500 g of the substance being examined for the quantity specified in the monograph and spread it in a thin layer. Detect the foreign matter by inspecting with the unaided eyes or with the use of 6X lens, separate, weigh and calculate the percentage present.

$$\text{Foreign matter, percent by weight} = \frac{\text{Mass of the foreign matter}}{\text{Mass of the sample}} \times 100$$

ANNEX C

[*Clause 5.1, Table 1, Sl No. v*)]

TEST METHOD FOR X-RAY OPACITY

C-1 APPARATUS

C-1.1 X-ray machine (rang up to 100 kV peak minimum).

C-1.2 Aluminium sheet 30 mm thick, have 99 percentage purity.

C-1.3 Lead sheet or lead rubber sheet, 2 mm minimum thickness.

C-2 TEST METHOD

Place the sample of X-ray detectable gauze under a 30mm thickness of a 99 percentage pure aluminium, in a centre of non-screen X-ray film positioned on a sheet of lead not less than 2mm thick, or on an equivalent thickness of lead rubber sheet masking any part of the film not covered by the test piece with

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2mm of lead or on an equivalent thickness of lead rubber sheet to prevent scattered radiation from affecting the film. Irradiate the sample and the aluminium simultaneously with X-rays at 70 kV peak, using an exposure sufficient to give a logarithmic photographic density of about 1.0 through a 10 mm thickness of the aluminium. When the developed radiograph is examined by transmitted light, the specimen image is clearly visible as a lighter area against a darker background.